

IN THE CIRCUIT COURT OF MADISON COUNTY  
STATE OF ILLINOIS

**FILED**

APR 12 2005

CLERK OF CIRCUIT COURT #8  
THIRD JUDICIAL CIRCUIT  
MADISON COUNTY, ILLINOIS

JOHN ALLEN, STEVE ELLIS, ANTHONY  
LEWIS, FRED HEATON, MICHAEL NEECE,  
NORRIS NICHOLSON, PEGGY MALECKI,

Plaintiffs,

v.

**MERCK & CO. INC.,**

Serve: Registered Agent  
The Corporation  
Company  
208 S. LaSalle St., Ste 814  
Chicago, IL 60604

**EXPRESS SCRIPTS, INC.**

Serve: Registered Agent  
CT Corporation System  
208 S. LaSalle St., Ste. 814  
Chicago, IL 60604

**WALGREEN CO., d/b/a WALGREENS,**

Serve: Registered Agent  
Allan M. Resnick  
200 Wilmot Road  
Deerfield, IL 60015

**WAL-MART STORES EAST, LP**

Serve: Registered Agent  
CT Corporation System  
208 So LaSalle St, Ste. 814  
Chicago, IL 60604-1101

Cause No.

05-377-MJR

Ex. 1

**WAL-MART STORES EAST, INC**

Serve: Registered Agent  
CT Corporation System  
208 So LaSalle St, Ste. 814  
Chicago, IL  
60604-1101

Defendants.

**COMPLAINT**

Come now plaintiffs, and for their complaint against defendants Merck & Co., Inc. ("Merck") and Express Scripts, Inc. ("Express Scripts"), Walgreen Co., d/b/a Walgreens ("Walgreens"), Wal-Mart Stores East, Inc and Wal-Mart Stores East, LP ("Wal-Mart"), (Express Scripts, Walgreens and Wal-Mart are hereinafter collectively referred to as the "seller defendants") alleges:

1. This is a proceeding brought by plaintiffs seeking damages for personal injuries and economic damages suffered as a result of the defective and dangerous pharmaceutical product Vioxx, which was manufactured, marketed, distributed and/or sold by Merck, Express Scripts, Walgreens and Wal-Mart, and to the general public.

**THE PARTIES**

2. John Allen is a citizen of the state of Illinois. John Allen was sold Vioxx by Wal-Mart and Express Scripts in Illinois. While on Vioxx, he suffered a heart attack in May 2003. He was 59 years old at the time of the incident. He

continued using Vioxx sold by Express Scripts and Wal-Mart for 16 months following his heart attack. His heart attack and health problems were caused or significantly contributed to be caused by Vioxx.

3. Steve Ellis is a citizen of the state of Illinois. While on Vioxx, he suffered a stroke. He continued to use Vioxx for one year following his stroke. He was 50 years old at the time of the incident. His stroke and health problems were caused or significantly contributed to be caused by Vioxx.

4. Anthony Lewis is a citizen of the state of Illinois. While on Vioxx, he suffered two heart attacks in June 2003 and July 2004. He used Vioxx for several years. He was 45 & 46 years old at the times of the incidents. His heart attacks and health problems were caused or significantly contributed to be caused by Vioxx.

5. Fred Heaton is a citizen of the state of Illinois. While on Vioxx, he suffered a heart attack in July 2004. His heart attack was caused or significantly contributed to be caused by Vioxx.

6. Michael Neece is a citizen of the state of Illinois. While on Vioxx, he suffered a heart attack in June 2003. He continued using 50 milligrams of Vioxx for 16 months following his heart attack. He was 48 years old at the time of the incident. His heart attack and health problems were caused or significantly contributed to be caused by Vioxx.

7. Norris Nicholson is a citizen of the state of Illinois. While on Vioxx, he suffered two heart attacks in January 2003. He was 48 years old at the time of incidents. His heart attacks and health problems were caused or significantly contributed to be caused by Vioxx.

8. Peggy Malecki is a citizen of the state of Illinois. Peggy Malecki was sold Vioxx by Walgreens in Illinois. While on Vioxx, she suffered heart and cardiovascular problems. She was 52 years old at the time. Her heart and cardiovascular problems were caused or significantly contributed to be caused by Vioxx.

9. As more particularly pleaded below, Plaintiffs maintain that Vioxx is defectively designed, inadequately tested, dangerous to human health, and lacked proper warnings as to the dangers associated with its use.

10. Defendant, Merck & Co., Inc. (hereinafter "Merck"), is a corporation organized and existing under the laws of the State of New Jersey, with its principal place of business at One Merck Drive, White House Station, New Jersey 08889.

11. At all times relevant hereto, Defendant Merck was and continues to be engaged in the business of testing, developing, manufacturing, distributing, licensing, labeling and marketing, either directly or indirectly through third parties or related entities, the pharmaceutical drug, Vioxx, in Illinois and throughout the United States.

12. Defendant Walgreen Co. ("Walgreens") is an Illinois corporation with its principal place of business located in Deerfield, Illinois. Walgreens sold Vioxx to one or more of the plaintiffs in the regular course of its business. Walgreens has offices in Madison County. Walgreens, for diversity purposes, is a citizen of the state of Illinois.

13. Wal-Mart Stores East, LP is a limited liability partnership. Wal-Mart Stores East, Inc, a Delaware Corporation with its principal place of business in Arkansas, is a general partner of Wal-Mart Stores East, LP. In addition, upon information and belief, numerous Arkansas and Illinois residents are general or limited partners of Wal-Mart Stores East LP. Wal-Mart sold Vioxx to one or more of the plaintiffs in the regular course of its business. Wal-Mart has offices in Madison County.

14. Defendant Express Scripts is an Delaware corporation with its principal place of business located in Missouri. Express Scripts sold Vioxx to one or more of the plaintiffs in the regular course of its business. Express Scripts has offices in Madison County.

**FACTS COMMON TO ALL COUNTS**

15. Vioxx is the brand name of rofecoxib, one of a class of drugs called "prostaglandins," which work to reduce inflammation and pain by providing analgesic and anti-inflammatory benefits to persons with, among other conditions, arthritis and muscle pain. Prostaglandins are COX (cyclooxygenase)

inhibitors; COX enzymes metabolize arachidonic acid to produce prostaglandins.

16. Vioxx is a COX-2 inhibitor, which is designed to produce prostaglandins at inflammatory sites, and to produce prostacyclin, a vasodilator and an inhibitor of platelet aggregation.

17. Defendant Merck submitted an Application to Market a New Drug for Human Use ("NDA") for rofecoxib to the United States Food and Drug Administration ("FDA") on November 23, 1998, for tablets, at doses of 12.5 mg and 25 mg, for relief of the signs and symptoms of osteoarthritis, the management of acute pain, and the treatment of primary dysmenorrhea. This application was denoted NDA 21-042 by the FDA.

18. Defendant Merck also submitted an Application to Market a New Drug for Human Use ("NDA") for rofecoxib to the United States Food and Drug Administration ("FDA") on November 23, 1998, for oral suspension, at doses of 12.5 mg/mL and 25 mg/mL, for relief of the signs and symptoms of osteoarthritis, the management of acute pain, and the treatment of primary dysmenorrhea. This application was denoted NDA 21-052 by the FDA.

19. On or about May 20, 1999, the FDA approved NDA 21-042 and NDA 21-052 (hereinafter the "NDA") for rofecoxib, for relief of the signs and symptoms of osteoarthritis, the management of acute pain, and the treatment of primary dysmenorrhea.



20. At the time the drug was approved by the FDA the labeling for rofecoxib stated, in the section entitled "Special Studies -- Upper Endoscopy in Patients with Osteoarthritis," "Treatment with VIOXX 25 mg daily or 50 mg daily was associated with a significantly lower percentage of patients with endoscopic gastroduodenal ulcers than treatment with ibuprofen 2400 mg daily. However, the studies cannot rule out at least some increase in the rate of endoscopic gastroduodenal ulcers when comparing VIOXX to placebo."

21. The "Warnings" section of the labeling for rofecoxib, at the time the drug was approved by the FDA, contains a section, "Gastrointestinal (GI) Effects -- Risk of GI Ulceration, Bleeding, and Perforation."

22. Defendant Merck submitted NDA-007 with the goal of establishing a gastrointestinal ("GI") safety claim for rofecoxib. In conjunction with the NDA, Defendant Merck performed the Vioxx GI Outcomes Research (VIGOR) Protocol, No. 088-04, entitled "A Double-Blind, Randomized, Stratified, Parallel-Group Study to Assess the Incidence of PUBs During Chronic Treatment With MK-0966 or Naproxen in Patients With Rheumatoid Arthritis: U.S. Cohort." The VIGOR study was performed from January 6, 1999 through March 17, 2000.

23. The objectives of the VIGOR study were to (1) "determine the relative risk of confirmed PUB (Perforation, Ulcers, Bleeding) in patients taking MK-0966 50 mg daily compared to patients in the group taking naproxen 1000 mg/day,"

and (2) "study the safety and tolerability of MK-0966 in patients with rheumatoid arthritis."

24. In industry-sponsored studies presented at the European United League Against Rheumatism (EULAR), an organization in which Merck is a member and corporate sponsor, in June of 2000, it was shown that Vioxx use resulted in a statistically significant increase in hypertension and stroke. Not only did Merck do nothing to further accurately publish these studies, or warn consumers, but it denied the results with respect to hypertension in the official publication of the American Pharmaceutical Association, *Pharmacy Today, Spin War Aside, Lessons Emerge From COX-2 Trials*, in August 2000, page 3.

25. Merck continued to deny the ill health effects associated with Vioxx while at the same time reaping profits obtained through its non-disclosure and concealment. Merck engaged in a massive advertising and sampling program and gained continued increases in the market share, which enhanced Merck's financial stability to the detriment of its consumers. As a result of Merck's scheme, it reaped more than \$2 billion in profit in the year 2000 alone, and appropriated approximately 23 percent share of the market.

26. Merck continued to profit from its scheme by withholding information from Plaintiff, the consuming public, and the health care industry. For example, in November of 2000, Merck caused the publication of a study in the New England Journal of Medicine in which it knowingly downplayed and/or withheld



the severity of cardiovascular risks associated with Vioxx consumption over naproxen consumption.

27. On or about August 29, 2001, the Journal of the American Medical Association (JAMA) published a peer-reviewed human epidemiologic study by the Cleveland Clinic Foundation, Cleveland, Ohio, Dr. D. Mukhisjee, et al., showing what Merck had concealed that the relative risk of developing a confirmed adjudicated thrombotic cardiovascular event (defined in the article as myocardial infarction, unstable angina, cardiac thrombus, resuscitated cardiac arrest, sudden or unexplained death, ischemic stroke, and transient ischemic attacks) among Vioxx users in Merck's trials, including VIGOR, at a 95% confidence interval ranged from 2.2 for event-free survival analysis, 2.38 compared to naproxen users, and 4.89 for developing serious cardiovascular events among aspirin-indicated patients. See Mukhisjee, D., et al., *Risk of Cardiovascular Events Associated With Selective Cox-2 Inhibitors*, J.A.M.A. 286:8, 954-959, Aug. 22/29, 2001. In addition, the annualized myocardial infarction rates for Vioxx users compared to placebo revealed a statistically significant increase among Vioxx users.

28. In the JAMA study, the authors stated that by decreasing PGI<sub>2</sub> production [Vioxx] may tip the natural balance between prothrombotic thromboxane A<sub>2</sub> and antithrombotic PGI<sub>2</sub>, potentially leading to an increase in thrombotic cardiovascular events. In a follow-up peer-reviewed study reported

in the Journal of the American College of Cardiology on or about February 6, 2002, Dr. Richard J. Bing conducted scientific testing and confirmed that the Cox-2 inhibitor tips the balance of prostacyclin/thromboxane in favor of thromboxane, leading to increased vascular and thrombotic events." Bing, R., & Lomnicka, M., *Why Do Cyclo-Oxygenase-2 Inhibitors Cause Cardiovascular Events?*, J.A.C.C., 39:3, Feb. 6, 2002. This is further supported by studies completed at the University of Pennsylvania. Cheng, Y., et al., *Role of Prostacyclin in the Cardiovascular Response to Thromboxane A2*, Journal of Science, V. 296:539-541, Apr. 19, 2002.

29. On September 17, 2001, Thomas W. Abrams, R.Ph., MBA, Director of the FDA Division of Drug Marketing, Advertising, and Communications, issued a "Warning Letter" to Raymond V. Gilmartin, President and CEO of Defendant Merck, relating to "promotional activities and materials for the marketing of Vioxx (rofecoxib) tablets."

30. The Warning Letter stated that Defendant Merck had "engaged in a promotional campaign for Vioxx that minimizes the potentially serious cardiovascular findings that were observed in the Vioxx Gastrointestinal Outcomes Research (VIGOR) study, and thus, misrepresents the safety profile for Vioxx." The letter further states:

Specifically, your promotional campaign discounts the fact that in the VIGOR study, patients on Vioxx were observed to have a four to five fold increase in myocardial infarctions (MIs) compared to patients on

the comparator non-steroidal anti-inflammatory drug (NSAID), Naprosyn (naproxen).

31. The eight (8) page Warning Letter outlines, in detail, the conduct of Defendant Merck that supports the FDA's issuance of the Warning Letter, and makes the following "**Conclusions and Requested Actions:**"

The promotional activities and materials described above minimize the potentially serious Cardiovascular findings that were observed in the VIGOR study, minimize the Vioxx / Coumadin drug interaction, omit crucial risk information associated with Vioxx therapy, contain unsubstantiated comparative claims, and promote unapproved uses. On December 16, 1999, we also objected to your dissemination of promotional materials for Vioxx that misrepresented Vioxx's safety profile, contained unsubstantiated comparative claims, and lacked fair balance.

Due to the seriousness of these violations, and the fact that your violative promotion of Vioxx has continued despite our prior written notification regarding similar violations, we request that you provide a detailed response to the issues raised in this Warning Letter on or before October 1, 2001.

This response should contain an action plan that includes a comprehensive plan to disseminate corrective messages about the issues discussed in this letter to the audiences that received these misleading messages. This corrective action plan should also include:

1. Immediately ceasing all violative promotional activities, and the dissemination of violative promotional materials for Vioxx.
2. Issuing a "Dear Healthcare provider" letter to correct false or misleading

impressions and information. This proposed letter should be submitted to us for review prior to its release. After agreement is reached on the content and audience, the letter should be disseminated by direct mail to all healthcare providers who were, or may have been exposed to the violative promotion.

3. A written statement of your intent to comply with "1" and "2" above.

32. On April 11, 2002, the FDA approved a supplemental application for the use of Vioxx (rofecoxib) for rheumatoid arthritis, adding this indication to the previously approved indications for osteoarthritis and pain. The FDA also approved new labeling, a "Dear Doctor" letter, and a new patient package insert. The labeling and the "Dear Doctor" letter contained information concerning the results of the VIGOR study.

33. The revised labeling further states that the administration of Vioxx 50 mg, was associated with a higher incidence of gastrointestinal symptoms.

**Clinical Studies in OA and RA with VIOXX 50 mg (Twice the highest dose recommended for chronic use)**

In OA and RA clinical trials which contained VIOXX 12.5 or 25 mg as well as VIOXX 50 mg, VIOXX 50 mg QD was associated with a higher incidence of gastrointestinal symptoms (abdominal pain, epigastric pain, heartburn, nausea and vomiting), lower extremity edema, hypertension, serious adverse experiences and discontinuation due to clinical adverse experiences compared to the recommended chronic doses of 12.5 and 25 mg (see DOSAGE AND ADMINISTRATION).

34. Further, the "Dear Doctor" letter, approved in conjunction with the revisions to the Vioxx labeling, outlines the changes to the Vioxx labeling.

35. The revised "Patient Information" sheet does not add any information about the results of the VIGOR study."

36. The "Patient Information" sheet is the only written document that is provided to a patient for whom Vioxx is prescribed.

37. Both the initial labeling and the revised labeling are ineffective because they do not properly advise physicians and patients of the potential cardiovascular, cardiothrombotic and/or gastrointestinal side effects of Vioxx.

38. Despite knowledge of the ineffectiveness of the warnings, and despite knowledge that Vioxx may cause serious cardiovascular and/or cardiothrombotic side effects, Defendant Merck has concealed and/or downplayed the dangers associated with Vioxx, and continues to market the drug in the United States and abroad. In its 2001 Annual Report, for example, Defendant Merck states:

The Company also noted that a number of federal and state lawsuits, involving individual claims as well as purported class actions, have been filed against the Company with respect to Vioxx. . . . The lawsuits include allegations regarding gastrointestinal bleeding and cardiovascular events. The Company believes that these lawsuits are completely without merit and will vigorously defend them.



39. Further, in its January 23, 2001 8-K filing with the Securities and Exchange Commission, Defendant fails to mention the cardiac and cardiothrombotic findings of the VIGOR study:

"Our results reflect the strength of our growth strategy," Mr. Gilmartin said. "Our five key products, **VIOXX**, ZOCOR, COZAAR/HYZAAR\*, FOSAMAX and SINGULAIR, drove Merck's performance for the year and created a powerful platform for growth." These products accounted for 57% of Merck's worldwide human health sales for 2000 and 61% for the fourth quarter.

"Each of the five medicines offers unique competitive advantages," Mr. Gilmartin said. **VIOXX**, a once-a-day medicine, is the only COX-2 indicated in the United States both for osteoarthritis and acute pain. Since its extraordinarily successful 1999 launch, **VIOXX** has become the world's fastest growing branded prescription arthritis medicine, and it is already Merck's second largest-selling medicine. In the United States, **VIOXX** now accounts for approximately 50 percent of new prescriptions in the COX-2 class, despite being second to market in this class in the United States. **VIOXX** achieved \$2.2 billion in sales for the full year 2000, with \$700 million in the fourth quarter.

A Food and Drug Administration (FDA) Advisory Committee meeting is scheduled for Feb. 8 to review labeling changes Merck has requested based on the strong results of the VIGOR Study. This 8,000-patient gastrointestinal outcomes research study, in which **VIOXX** reduced the risk of serious gastrointestinal complications by half compared to the NSAID naproxen, was published in November in THE NEW ENGLAND JOURNAL OF MEDICINE. Another study, presented in November, showed that **VIOXX** significantly reduced moderate-to-severe acute pain after dental surgery to a greater degree compared to codeine combined with acetaminophen.



40. Despite the foregoing, Defendant Merck has continued to represent to consumers that Vioxx is safe, and that any cardiovascular and/or cardiothrombotic side effects are not associated with the drug. The Defendant has also downplayed any potential gastrointestinal side effects of the drug, promoting it as safer and more efficacious than other medications approved for treatment of similar conditions.

41. Pursuant to prescriptions received from their treating physician, plaintiffs regularly purchased and ingested Vioxx for various periods of time. Plaintiffs now suffers from heart attacks, strokes, TIAs, coronary artery disease, atherosclerosis, blood clots, and other diseases caused by the use of Vioxx.

42. Vioxx is primarily prescribed to reduce pain from inflammation. However, the defendants failed to conduct sufficient research in manufacturing and marketing Vioxx to determine the severity of the drugs' potential side effects. Defendants also withheld adverse reports, or gave incorrect information about such reports, they had received about side effects such as heart attacks and strokes. As a result of defendants' failure and the undisclosed defects of Vioxx, plaintiffs have sustained heart attacks, strokes, TIAs, and other ill-effects.

43. Defendant Merck & Company, Inc. is a New Jersey corporation with its principal place of business located in New Jersey. Merck is engaged in the business of producing, marketing and distributing pharmaceutical products for sale to the general public and is the manufacturer of Rofecoxib, distributed

under the brand-name Vioxx. Merck conducts business in the State of Illinois, and at all times relevant hereto, it developed, manufactured and sold the pharmaceutical drug Vioxx in the State of Illinois.

#### **JURISDICTION AND VENUE**

44. Defendants are subject to the *in personam* jurisdiction of this Court, and venue is proper herein, by virtue of the fact that defendants did and/or does business within the state of Illinois and committed torts in whole or in part in this state against plaintiffs, as more fully set forth herein. Defendants advertised in Illinois and in Madison County and made material omissions and representations in this county as well as sold Vioxx in Madison County.

45. There is no federal subject matter jurisdiction because no federal question is raised and there is no jurisdiction based on diversity of citizenship because plaintiffs and non-diverse defendants are citizens of the same state.

46. Venue is proper in this Court because seller defendants have offices or do business in Madison County; Merck does business in Madison County and has offices in Madison County, or part of the transaction took place in Madison County.

47. The applicable statute of limitations is tolled based on defendants' fraudulent concealment of the dangers and adverse side effects of Vioxx from plaintiffs as more fully stated herein. Additionally, for the reasons stated herein,

all defendants are equitably estopped from raising the statute of limitations defense.

**COUNT I**

**Strict Products Liability/Defective Design --**  
**Against Merck**

Come now plaintiffs and for Count I of their complaint against defendant Merck allege:

48. Plaintiffs incorporate all allegations in the preceding paragraphs as if fully set forth in this Count.

49. Defendant Merck designed, produced, manufactured and injected into the stream of commerce, in the regular course of its business, the pharmaceutical drug Vioxx which it knew would be used by plaintiffs and others.

50. At the time the Vioxx was manufactured and sold to plaintiffs by Merck, it was defective in design and unreasonably dangerous, subjecting users to risks of heart attacks, strokes, and other illnesses which exceeded the benefits of the products, and for which other safer products were available.

51. Alternatively, when the Vioxx products were manufactured and sold to plaintiffs by defendants, the products were defective in design and formulation, making use of the products more dangerous than other drugs for pain relief.

52. The Vioxx sold to plaintiffs reached plaintiffs without substantial change. Plaintiffs was unaware of the dangerousness of the products until after their use and the development of heart disease, requiring a quadruple bypass. Plaintiffs ingested the Vioxx without making any changes or alterations.

53. As a direct and proximate result of the defective and dangerous design of the Vioxx, plaintiffs has been damaged.

54. Defendant's conduct was done with conscious disregard for the safety of users of Vioxx, including plaintiffs, justifying an award of punitive damages.

WHEREFORE, plaintiffs demand judgment in their favor and against Merck for:

A. A fair and just amount of actual damages in an amount to be proved at trial;

B. Costs of suit;

C. Pre-judgment and post-judgment interest;

D. Punitive damages in a fair and reasonable amount to punish and deter Merck and others from engaging in the wrongful conduct; and

E. Such other and further relief as the Court deems just and proper under the circumstances.

#### **COUNT II**

#### **Strict Products Liability/Failure to Warn -- Against Merck**

Come now plaintiffs and for Count II of their complaint against defendant Merck alleges:

55. Plaintiffs incorporate all allegations in the preceding paragraphs as if fully set forth in this Count.

56. The Vioxx manufactured and supplied by Merck was unaccompanied by proper and adequate warnings regarding all adverse side effects associated with the use of Vioxx, and the comparative severity and duration of the adverse effects. The warnings given by Merck did not accurately reflect the symptoms, type, scope or severity of the side effects.

57. Merck failed to perform adequate testing and study Vioxx prior to marketing it or properly analyze and warn based on its VIGOR study. Such adequate testing, study or analysis of the VIGOR would have shown that Vioxx possessed serious life threatening side effects; with respect to which full and proper warnings accurately and fully reflecting symptoms, type of illness, scope and severity should have been given with respect to the use of Vioxx.

58. Merck also failed to act properly on adverse reports it received about Vioxx, and failed to properly study Vioxx pre-market as well as post market and analyze and follow up on its VIGOR study as well as other studies.

59. Merck also failed to effectively warn users and physicians that numerous other methods of pain relievers, including Ibuprofen, Naproxen, and/or aspirin were safer.

60. Merck failed to give adequate post-marketing warnings or instructions for the use of Vioxx because after Merck knew or should have known of the risk of injury from Vioxx use, Merck failed to provide adequate warnings to users or consumers and continued to aggressively promote the product to doctors, hospitals, and directly to consumers.

61. As a direct and proximate result of defendant's failure to warn of the potentially severe side effects of the Vioxx products, as well as the other conduct mentioned in this Count, plaintiffs have been damaged.

62. Merck's conduct was done with conscious disregard for safety, justifying an award of punitive damages.

WHEREFORE, plaintiffs demand judgment in their favor and against Merck for:

A. A fair and just amount of actual damages in an amount to be proved at trial;

B. Costs of suit;

C. Pre-judgment and post-judgment interest;

D. Punitive damages in a fair and reasonable amount to punish and deter Merck and others from engaging in the wrongful conduct; and

E. Such other and further relief as the Court deems just and proper under the circumstances.

**COUNT III**



**Strict Products Liability/Sale of Defective Product -- Against the seller defendants**

Come now plaintiffs and for Count III of their complaint against the seller defendants allege:

63. Plaintiffs incorporate all allegations in the preceding paragraphs as if fully set forth in this Count.

64. The Vioxx sold by seller defendants was defective and unreasonably dangerous when sold, and unaccompanied by proper and adequate warnings regarding all possible adverse side effects associated with the use of Vioxx, and the comparative severity and duration of the adverse effects. The warnings accompanying the Vioxx did not accurately reflect the symptoms, type, scope or severity of the side effects. The seller defendants knew or should have known of these side effects due to the FDA sanctioning Merck for its misleading advertising and Dear Doctor letters Merck was required by the FDA to send, as well as other information available to a prudently informed seller of Vioxx.

65. The Vioxx sold to plaintiffs was unaccompanied by a warning to plaintiffs that numerous other methods of pain relievers, including but not limited to Ibuprofen and/or aspirin were safer.

66. As a direct and proximate result of the seller defendants selling a defective product, it is strictly liable for the damages the Vioxx caused plaintiffs.

WHEREFORE, plaintiffs demand judgment in their favor and against the seller defendants for:

A. A fair and just amount of actual damages in an amount to be proved at trial;

B. Costs of suit;

C. Pre-judgment and post-judgment interest;

D. Such other and further relief as the Court deems just and proper under the circumstances.

#### COUNT IV

#### Negligent Design--Against Merck

Come now plaintiffs and for Count IV of their complaint against defendant Merck alleges:

67. Plaintiffs incorporate all allegations in the preceding paragraphs as if fully set forth in this Count.

68. Defendant Merck designed, produced, manufactured and injected into the stream of commerce, in the regular course of its business, the pharmaceutical drug Vioxx which it knew would be used by plaintiffs and others.

69. At the time the Vioxx was manufactured and sold to plaintiffs by Merck, it was defective in design and unreasonably dangerous, subjecting users to risks of heart attacks, strokes, blood clots, and other illnesses which exceeded the benefits of the products, and for which other safer products were available.

70. Alternatively, when the Vioxx products were manufactured and sold to plaintiffs by defendant, the product was defective in design and formulation, making use of the product more dangerous than other drugs for pain relief.

71. The Vioxx sold to plaintiffs reached plaintiffs without substantial change. Plaintiffs were unaware of the dangerousness of the product until after their use and the development of heart disease and a quadruple bypass. Plaintiffs ingested the Vioxx without making any changes or alterations.

~~72. In designing and testing Vioxx, Merck failed to exercise the ordinary~~  
care that a careful and prudent drug manufacturer would exercise in the same or similar circumstances.

73. As a direct and proximate result of the negligent design of the Vioxx, plaintiffs have been damaged.

74. Merck's conduct was done with conscious disregard for the safety of users of Vioxx, including plaintiffs, justifying an award of punitive damages.

WHEREFORE, plaintiffs demand judgment in their favor and against Merck for:

- A. A fair and just amount of actual damages in an amount to be proved at trial;
- B. Costs of suit;
- C. Pre-judgment and post-judgment interest;
- D. An award of punitive damages; and

E. Such other and further relief as the Court deems just and proper under the circumstances.

**COUNT V**

**Negligence, Failure to Warn--Against Defendant Merck**

Come now plaintiffs and for Count V of their complaint against defendant Merck, alleges:

75. Plaintiffs incorporate all allegations in the preceding paragraphs as is fully set forth in this Count:

76. Merck owed a duty to warn of any dangerous defects or side effects; a duty to assure its product did not cause users unreasonable and dangerous risks, reactions, and side effects; and a duty to provide adequate post market surveillance and warnings as it learned of Vioxx's substantial dangers.

77. Merck breached its duty of reasonable care to plaintiffs in that Merck failed to:

a. Conduct sufficient testing which, if properly performed, would have shown that Vioxx had serious side effects, including heart attacks, strokes, hypertension, atherosclerosis, blood clots, and other serious side effects, and warn users of those risks; and/or

b. Include adequate warnings with the Vioxx products that would alert users to the potential risks and serious side effects of the drugs; and/or

c. Warn plaintiffs that use of Vioxx carried a risk of death or permanent disability from heart attack, strokes, blood clots, other cardiovascular disorders and other serious side effects; and/or

d. Advise the FDA, the health care industry, and the public about the adverse reports it had received regarding Vioxx; and/or

e. Other appropriate warnings.

78. Merck should have known that Vioxx caused unreasonably dangerous risks and serious side effects of which the general public would not be aware.

Merck nevertheless advertised, marketed and promoted its product knowing there were safer methods and products for pain control.

79. As a direct and proximate result of Merck's negligence and breaches of its duty of reasonable care, plaintiffs have been damaged.

WHEREFORE, plaintiffs demand judgment in their favor and against defendant Merck for:

A. A fair and just amount of actual damages in an amount to be proved at trial;

B. Costs of suit;

C. Pre-judgment and post-judgment interest;

D. Punitive damages in a fair and reasonable amount to punish and deter Merck and others from engaging in the wrongful conduct; and

E. Such other and further relief as the Court deems just and proper under the circumstances.

**COUNT VI**

**Negligence, Failure to Warn--Against the seller defendants**

Come now plaintiffs and for Count VI of their petition against the seller defendants allege:

80. Plaintiffs incorporate all allegations in the preceding paragraphs as if fully set forth in this Count:

81. The seller defendants owed a duty to warn of any dangerous defects or side effects; a duty to assure the products they sold did not cause users unreasonable and dangerous risks, reactions, and side effects; and a duty to provide adequate post sale warnings as it learned of Vioxx's substantial dangers.

82. The seller defendants knew or should have known that Vioxx caused unreasonably dangerous risks and serious side effects of which the general public would not be aware, based on the following information, including but not limited to, the FDA sanctions of Merck, the Dear Doctor letters Merck sent to doctors and other health care providers, the medical literature regarding Vioxx, the medical literature regarding Vioxx based on Merck studies, industry sponsored studies and or information available to the reasonably prudent seller. The seller defendants nevertheless sold Vioxx without adequate warnings of the



dangerousness of Vioxx and knowing that there were safer methods and products for pain control.

83. Upon information and belief, the seller defendants knew or should have known about the respective health conditions of the plaintiffs that they sold Vioxx to based on their health histories and records of other prescriptions that are in the seller defendants' possession.

84. Upon information and belief, the seller defendants provided warnings along with Vioxx that contained inaccurate information in that these warnings failed to warn that Vioxx had serious side effects, including heart attacks, strokes, hypertension, atherosclerosis, blood clots, and others, and these are side effects that the seller defendants knew or should have known of, and that plaintiffs should have been counseled regarding the serious side effects of Vioxx in light of the health problems that the seller defendants knew plaintiffs had.

85. Defendants breached their duty of reasonable care to plaintiffs in that defendants failed to:

- a. Warn that Vioxx had serious side effects, including heart attacks, strokes, hypertension, atherosclerosis, blood clots, and other serious side effects; and/or

b. Include adequate warnings with the Vioxx products that would alert users to the potential risks and serious side effects of the drugs; and/or

c. Warn plaintiffs that use of Vioxx carried a risk of death or permanent disability from heart attack, strokes, blood clots, other cardiovascular disorders and other serious side effects; and/or

d. Advise the FDA, the health care industry, and the public about the adverse reports it had received regarding Vioxx; and/or

e. Provide an accurate warning when warning the plaintiffs that Vioxx had serious side effects, including heart attacks, strokes, hypertension, atherosclerosis, blood clots, and others, and warn users of those side effects which seller defendants knew or should have known of and counsel on safer alternatives such as aspirin or ibuprofen; and/or

f. Other appropriate warnings.

86. As a direct and proximate result of defendants' negligence and breaches of their duty of reasonable care, plaintiffs have been damaged.

WHEREFORE, plaintiffs demand judgment in their favor and against the seller defendants for:

A. A fair and just amount of actual damages in an amount to be proved at trial;

B. Costs of suit;

C. Pre-judgment and post-judgment interest;

D. Such other and further relief as the Court deems just and proper under the circumstances.

#### COUNT VII

##### **Deceptive Trade Practices Acts-- Against Merck**

Come now plaintiffs and for Count VII of their complaint against defendant Merck allege:

87. Plaintiffs incorporate all allegations in the preceding paragraphs as if fully set forth in this Count.

88. Plaintiffs bring this action pursuant to 815 ILCS 505, et seq. (The Illinois Consumer Fraud and Deceptive Practices Act), in that he purchased and used Vioxx for their personal use and thereby suffered ascertainable loss as a result of Merck's actions in violation of the Illinois consumer fraud statute.

89. Unfair or deceptive acts or practices are defined and declared unlawful in Illinois. The unfair or deceptive acts or practices as defined in the statute include, "the use of any deception, fraud, false pretense, false promise, misrepresentation or concealment, suppression or omission of any material fact . . . in the conduct of any trade or commerce."

90. Merck violated the Act by its use of false and misleading misrepresentations or omissions of material fact in connection with the sale of Vioxx. Merck communicated the purported benefits of Vioxx, while failing to

disclose the serious and dangerous side effects related to the use of its product, and in fact actually concealing from health care providers the adverse cardiovascular effects of Vioxx.

91. In this regard, Merck, including but not limited to, created a "dodgeball Vioxx" training package for its sales force, which instructed the individual defendants named in this count to duck doctors and health care providers' questions about Vioxx's possible cardiovascular side effects. Merck's sales representations followed its instructions and concealed, omitted, and suppressed these material facts when making sales calls to health care providers.

92. As a result of violating the Illinois consumer fraud statute, Merck is liable to plaintiffs for actual damages, costs and reasonable attorneys' fees, and for such additional relief as the Court may deem appropriate.

WHEREFORE, plaintiffs demand judgment in its favor and against defendant Merck for:

- A. A fair and just amount of actual damages in an amount to be proved at trial;
- B. Costs of suit;
- C. Pre-judgment and post-judgment interest;
- D. Punitive damages in a fair and reasonable amount to punish and deter Merck and others from engaging in the wrongful conduct; and

E. Such other and further relief as the Court deems just and proper under the circumstances.

#### COUNT VIII

##### Negligent Misrepresentation—against defendants Merck

Come now plaintiffs and for Count VIII of their complaint against Merck, allege:

93. Plaintiffs reallege the allegations in the preceding paragraphs as if fully set out herein:

94. Merck misrepresented to plaintiffs and/or their treating physicians the potential serious cardiovascular findings that were observed in the VIGOR study, minimized the Vioxx/Coumadin drug interaction, omitted crucial risk information associated with Vioxx, misrepresented Vioxx safety profile and represented that Vioxx was safe, and that any cardiovascular and/or cardio thrombotic side effects were not associated with the drug.

95. These representations were made with the actual knowledge of Merck.

96. The representations set forth *supra* were material to plaintiffs and/or their treating physicians to prescribe and maintain plaintiffs' prescription of Vioxx.

97. The representations were made either without knowing of the truth or falsity of the representations or knew or should have known that the representations being made were false and, therefore, defendant failed to

exercise reasonable care in making the representations in the scope and course of their employment in marketing Vioxx to individual consumers, plaintiffs' treating physicians, hospitals, and other health care providers.

98. Merck intended for plaintiffs and/or their treating physicians to rely upon the material misrepresentations to induce them to initially prescribe Vioxx and continue plaintiffs on Vioxx.

99. Plaintiffs justifiably relied on the representations which were made directly to their treating physicians, with Merck knowing that plaintiffs were in a limited group who Merck knew would rely upon the information.

100. As a direct result of Merck's negligent misrepresentation, personal injuries and actual damages in an amount to be proved at trial. The negligent misrepresentations caused or substantially contributed to cause plaintiffs' damages.

WHEREFORE, plaintiffs pray for a judgment against defendant Merck for:

- A. Actual and compensatory damages in an amount to be proved at trial;
- B. Costs of suit;
- C. Pre and post judgment interest; and
- D. Such other and further relief as the Court deems just and proper under the circumstances.

**COUNT IX**



**Fraudulent Omission/Concealment—defendant Merck**

Come now plaintiffs and for Count IX of their complaint against defendant Merck allege:

101. Plaintiffs reallege the allegations in the preceding paragraphs as if fully set forth herein.

102. Merck had actual knowledge of the cardiothrombotic effects of Vioxx. Despite having knowledge of the cardiothrombotic effects of Vioxx, Merck actively concealed and omitted to disclose those effects when marketing Vioxx to doctors, health care providers, and to the general public through direct advertisements.

103. At the time these omissions were made, Merck had knowledge of the substantial and significant cardiothrombotic effects of Vioxx.

104. Merck omitted to inform plaintiffs of the true cardiothrombotic and other adverse health effects of Vioxx. Merck further downplayed the results of various studies showing the cardiothrombotic effects and explaining the cardiothrombotic effects of Vioxx as set forth in the VIGOR study, it withheld adverse reports or gave incorrect information about the reports it received about the side effects of Vioxx such as heart attacks and strokes. It further instructed and had a training manual for their sales force to dodge and mislead doctors when they asked questions about the cardiothrombotic effects of Vioxx.

105. Merck's failure to disclose material facts constituted fraudulent concealment. Merck sanctioned approved and/or participated in the failure to disclose.

106. Merck had a duty to speak because it had superior knowledge regarding the adverse health effects of Vioxx as set forth herein.

107. The information not disclosed by Merck was unavailable to plaintiffs and/or their treating health care professionals. Merck knew the information was unavailable yet approved and participated in instructing its agents, servants and employees to not disclose this information in order to promote the sales of Vioxx over other Cox 2 inhibitors as well as any non-steroidal anti-inflammatory such as Ibuprofen, Naproxin, and aspirin.

108. Plaintiffs were diligent in attempting to seek the information by consulting with their physicians.

109. The information not disclosed by Merck was not within the reasonable reach of plaintiffs and/or their treating physicians and was not discoverable by plaintiffs and/or their treating physicians in the exercise of reasonable care.

110. The non-disclosed information was material, Merck knew it was not disclosing complete information and intended that plaintiffs and/or their treating physicians act upon the non-disclosed information in the manner reasonably contemplated.

111. Plaintiffs and/or their treating physician were ignorant as to the undisclosed information and had a right to rely on full disclosure.

112. If plaintiffs and/or their treating physicians had known the complete information, they would not have prescribed and/or plaintiffs would not have taken Vioxx as evidenced by Merck withdrawing it from the market in September 2004.

113. Merck's non-disclosure of information was outrageous due to their evil motive or reckless indifference to the rights of plaintiffs, justifying an award of punitive damages.

WHEREFORE, plaintiffs demand judgment in their favor and against defendant Merck for:

A. A fair and just amount of actual damages in an amount to be proved at trial;

B. Costs of suit;

C. Pre-judgment and post-judgment interest;

D. Punitive damages in a fair and reasonable amount to punish and deter Merck and others from engaging in the wrongful conduct; and

E. Such other and further relief as the Court deems just and proper under the circumstances.

**COUNT X**

**Common Law Fraud--**  
**Against Merck**

Come now plaintiffs and for Count X against Merck alleges:

114. Plaintiffs incorporate all allegations in the preceding paragraphs as if fully set forth in this Count.

115. Merck, at all relevant times, made false representations and omissions to plaintiff and other members of the public, including but not limited to, that Vioxx was safe, had been adequately tested to determine safety, and did not present life-threatening dangers.

116. These representations and omissions, as set forth in the above paragraphs, were false. The true facts were that Vioxx were not safe, had not been adequately tested, and had dangerous and life-threatening side effects. When Merck made the representations, it knew them to be false, and said representations were made by Merck with the intent to deceive plaintiffs and/or their prescribing physicians and with the intent to induce plaintiffs to use the Vioxx manufactured by Merck.

117. Plaintiffs and/or their physicians reasonably relying upon the false representations and omissions, plaintiffs' physicians prescribed Vioxx, plaintiffs used Vioxx. Plaintiffs would not have done so if they had known the true facts. In using Vioxx, plaintiffs exercised ordinary care.

118. As a direct and proximate result of the aforesaid fraudulent conduct, Merck caused plaintiffs to suffer the damages and injuries herein alleged.

119. Merck's conduct was outrageous due to its evil motive or reckless indifference to the rights of plaintiffs, justifying an award of punitive damages.

WHEREFORE, plaintiffs demand judgment in their favor and against defendant Merck for:

- A. A fair and just amount of actual damages in an amount to be proved at trial;
- B. Costs of suit;
- C. Pre-judgment and post-judgment interest;
- D. Punitive damages in a fair and reasonable amount to punish and deter Merck and others from engaging in the wrongful conduct; and
- E. Such other and further relief as the Court deems just and proper under the circumstances.

#### **COUNT XI**

##### **Breach of Warranty--Against the seller defendants**

Come now plaintiffs and for Count XI of their complaint against the seller defendants allege:

120. Plaintiffs incorporate all allegations in the preceding paragraphs as if fully set forth in this Count.

121. Plaintiffs purchased the defective and dangerous Vioxx drugs from the seller defendants.

122. In selling Vioxx to plaintiffs, seller defendants expressly and impliedly warranted that Vioxx was safe for its intended use, was free from manufacturing or production defects, and would perform as indicated. Seller defendants also expressly and impliedly warranted that Vioxx caused no side effects other than those listed in the package insert.

123. Seller defendants breached these warranties by selling to plaintiffs Vioxx that was not of merchantable quality, was unsafe and whose potential side effects were substantially undisclosed.

124. As a direct and proximate result of the seller defendants' breach of express and implied warranties, plaintiffs have been damaged.

WHEREFORE, plaintiffs demand judgment in their favor and against the seller defendants for:

- A. Actual and compensatory damages in an amount to be proved at trial;
- B. Costs of suit;
- C. Pre and post judgment interest; and
- D. Such other and further relief as the Court deems just and proper under the circumstances.

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